



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Colloca, Stefano

Serial No. 09/831,182

Filed: July 18, 2001

For: CELLS FOR THE PRODUCTION OF HELPER
DEPENDENT ADENOVIRAL VECTORS

Art Unit: 1648

Examiner: Winkler, U.

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR 1.97

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).
2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.
3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

07/16/2003 SDIRETA1 00000003 132755 09831182

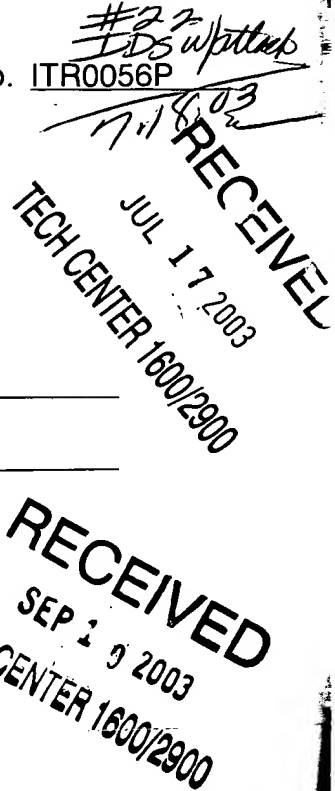
02 FC:1806 180.00 DA

MERCK & CO., INC.

By

Date

July 10, 2003



INFORMATION DISCLOSURE STATEMENT

4. Except for Cite Nos. _____, copies of the references listed on the attached form are not enclosed because they have been submitted to or cited by the Office in a related application as follows:

| RELATED APPLICATION | | |
|---------------------|-------------|------------|
| U. S. SERIAL NUMBER | FILING DATE | MERCK CASE |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

upon which the instant application relies for an earlier filing date under 35 U.S.C. 120. Therefore, pursuant to 37 C.F.R. 1.98(d), copies of these references are not enclosed herewith. If this is inconvenient, additional copies will be submitted upon request.

5. In accordance with 37 C.F.R. 1.97, (check one)

- ☐ the attached information is filed within three months of the filing date of the captioned case.
- ☐ the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.
- ☒ the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action or Notice of Allowance. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
- ☐ the undersigned certifies that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
- ☐ the undersigned certifies that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.

Respectfully submitted,



By: Anna L. Cocuzzo

Attorney _____ For Applicant(s)

Reg. No. 42,452

MERCK & CO., INC.

Patent Dept., RY60-30

P.O. Box 2000

Rahway, N.J. 07065-0907

(732)594- 1273

Date: July 10, 2003

WN

RECEIVED

JUL 17 2003

TECH CENTER 1600/2900

RECEIVED
SEP 12 2003
TECH CENTER 1600/2900

| | | | |
|-----------------------|--|--------------------|--|
| Examiner Signature | | Date Considered | |
|-----------------------|--|--------------------|--|

SEND TO: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE

STATEMENT BY APPLICANT

(use as many sheets as necessary)

2

of

3

COMPLETE IF KNOWN

| | |
|------------------------|------------------|
| Application Number | 09/831,182 |
| Filing Date | July 18, 2001 |
| First Named Inventor | Colloca, Stefano |
| Group Art Unit | 1648 |
| Examiner Name | Winkler, U. |
| Attorney Docket Number | ITR0056P |

OTHER NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No. | Include name of the author, title, date, page(s), volume-issue number(s) and place of publication. |
|--------------------|----------|--|
| | | Baron, U. et al. "Co-regulation of two gene activities by tetracycline via a bidirectional promoter", Nucleic Acids Research, 1995, Vol. 23, pp. 3605-3606 |
| | | Brough, D. et al. "A Gene Transfer Vector-Cell Line System for Complete Functional Complementation of Adenovirus Early Regions E1 and E4", Journal of Virology, 1996, Vol. 70, pp. 6497-6501 |
| | | Bett, A. et al. "An efficient and flexible system for construction of adenovirus vectors with insertions or deletions in early regions 1 and 3", Proc. Natl. Acad. Sci. USA, 1994, Vol. 91, pp. 8802-8806 |
| | | Calos, M. "The potential of extrachromosomal replicating vectors for gene therapy", TIG, 1996, Vol. 12, pp. 463-466 |
| | | Calos, M. "Stability without a centromere", Proc. Natl. Acad. Sci. USA, 1998, Vol. 95, pp. 4084-4085 |
| | | Deuschle, U. et al. "Tetracycline-Reversible Silencing of Eukaryotic Promoters", Molecular and Cellular Biology, 1995, Vol. 15, pp. 1907-1914 |
| | | Engelhardt, J. et al. "Ablation of E2A in recombinant adenoviruses improves transgene persistence and decreases inflammatory response in mouse liver", Proc. Natl. Acad. Sci. USA, 1994, Vol. 91, pp. 6196-6200 |
| | | Freundlieb, S. et al. "A Tetracycline Controlled Activation/Repression System with Increased Potential for Gene Transfer into Mammalian Cells", The Journal of Gene Medicine, 1999, Vol. 1, pp. 4-12 |
| | | Gossen, M. et al. "Transcriptional Activation by Tetracyclines in Mammalian Cells", Science, 1995, Vol. 268, pp. 1766-1769 |
| | | Hitt, M. et al. "Techniques for Human Adenovirus Vector Construction and Characterization", Methods in Molecular Genetics, 1995, Vol. 7, pp. 13-30 |
| | | Hitt, M. et al. "Human Adenovirus Vectors for Gene Transfer into Mammalian Cells", Advances in Pharmacology, 1997, Vol. 40, pp. 137-206 |
| | | Kozarsky, K. et al. "In Vivo Correction of Low Density Lipoprotein Receptor Deficiency in the Wantanabe Heritable Hyperlipidemic Rabbit with Recombinant Adenoviruses", The Journal of Biological Chemistry, 1994, Vol. 269, pp. 13695-13702 |
| | | Krougliak, V. et al. "Development of Cell Lines Capable of Complementing E1, E4, and Protein IX Defective Adenovirus Type 5 Mutants", Human Gene Therapy, 1995, Vol. 6, pp. 1575-1586 |
| | | No, D. et al. "Ecdysone-inducible gene expression in mammalian cells and transgenic mice", Proc. Natl. Acad. Sci. USA, 1996, Vol. 93, pp. 3346-3351 |
| | | Parks, R. et al. "A helper-dependent adenovirus vector system: Removal of helper virus by Cre-mediated excision of the viral packaging signal", Proc. Natl. Acad. Sci. USA, 1996, Vol. 93, pp. 13565-13570 |

Examiner
SignatureDate
Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

SEND TO: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

Please type a plus sign (+) inside this box.

Approved for use through 4/30/2003. OMB 0651-0031
SUBSTITUTE for PTO/SR/08 (03-03), Information Disclosure Statement by Applicant
Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE

STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

3

of

3

Application Number 09/831,182

Filing Date July 18, 2001

First Named Inventor Colloca, Stefano

Group Art Unit 1648

Examiner Name Winkler, U.

Attorney Docket Number ITR0056P

COMPLETE IF KNOWN

RECEIVED
JUL 17 2003
TECH CENTER 1600/2900

OTHER NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No. | Include name of the author, title, date, page(s), volume-issue number(s) and place of publication. |
|--------------------|----------|--|
| | | Spencer, D. et al. "Conrolling Signal Transduction with Synthetic Ligands", Science, 1993, Vol. 262, pp. 1019-1024 |
| | | Wang, Y. et al. "A regulatory system for use in gene transfer", Proc. Natl. Acad. Sci. USA, 1994, Vol. 91, pp. 8180-8184 |
| | | Yang, Y. et al. "Cellular immunity to viral antigens limits E1-deleted adenoviruses for gene therapy", Proc. Natl. Acad. Sci. USA, 1994, Vol. 91, pp. 4407-4411 |
| | | Amalfitano, A. et al. "Production and Characterization of Improved Adenovirus Vectors with the E1, E2b, and E3 Genes Deleted", Journal of Virology, 1998, Vol. 72, pp. 926-933 |
| | | Dedieu, J. et al. "Long-Term Gene Delivery into the Livers of Immunocompetent Mice with E1/E4-Defective Adenoviruses", Journal of Virology, 1997, Vol. 71, pp. 4626-4637 |
| | | Gorziglia, M. et al. "Elimination of both E1 and E2a from Adenovirus Vectors Further Improves Prospects for In Vivo Human Gene Therapy", Journal of Virology, 1996, Vol. 70, pp. 4173-4178 |
| | | Gao, G. et al. "Biology of Adenovirus Vectors with E1 and E4 Deletions for Liver-Directed Gene Therapy", Journal of Virology, 1996, Vol. 70, pp. 8934-8943 |
| | | Recchia, A. et al. "Site-specific integration mediated by a hybrid adenovirus/adeno-associated virus vector", Proc. Natl. Acad. Sci. USA, 1999, Vol. 96, pp. 2615-2620 |
| | | Rittner, K. et al. "Conditional Repression of the E2 Transcription Unit in E1-E3-Deleted Adenovirus Vectors is Correlated with a Strong Reduction in Viral DNA Replication and Late Gene Expression In Vitro", Journal of Virology, 1997, Vol. 71, pp. 3307-3311 |
| | | Zhang, Y et al. "A new logic for DNA engineering using recombination in <i>Escherichia coli</i> ", Nature Genetics, 1998, Vol. 20, pp. 123-128 |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

RECEIVED
SEP 1 2003
TECH CENTER 1600/2900

Examiner Signature

Date Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

SEND TO: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

Computer generated form "IDS Form" (IDS Folder), Merck & Co., Inc., 06/27/2003